

## II. REMARKS/ARGUMENTS

### A. Status of the Claims

Claims 69-91, 93-94, 96-107 are currently pending. Claims 91, 106, and 107 have been amended without prejudice. Claims 92 and 95 have been cancelled without prejudice. It is respectfully submitted that no new matter has been added by virtue of this amendment.

### B. Election/Restrictions

The Examiner stated that “it is unclear at this point which claims are to be withdrawn as not being drawn to the elected invention, since the invention is unclear in light of the claim language.”

It is respectfully submitted that the claims have been amended to clearly define the invention as described below.

### C. 35 U.S.C. §112, 1<sup>st</sup> Paragraph

Claim 69-107 were rejected under 35 U.S.C. §112, first paragraph, “as failing to comply with the enablement requirement.” In making the rejection, the Examiner stated that “[t]he invention, as claimed, is drawn to a method of delivery of a therapeutic agent or a diagnostic agent comprising three components (1. polymer, 2. a therapeutic or diagnostic agent, and 3. a cell uptake promoter) . . . . However, Applicant has only elected two compounds as the invention, namely PEG (polymer) conjugate to a retro inversion peptide (i.e. elected SEQ ID NOS: 1-8). Further the Examiner stated that “[t]he specification has not clearly defined that there are three respective compounds conjugated together, as claimed.

This rejection is traversed. In the previous Office Action, the Examiner stated that “Applicant is required to elect **a specific composition (one compound structure of a polymer covalently bound to agent) or compound (agent, one compound structure of Formula A or B)** as drawn to the elected group . . . .” See Office Action mailed

12/11/2003, page 5. In response, Applicant elected “a polymer” and “a therapeutic or diagnostic agent” as requested by the Examiner. Applicants did not indicate in the previous response that the elected invention is the conjugation of only two compounds, but merely elected a polymer and an agent as requested by the Examiner. Claim 69 clearly sets forth three components as indicated by the Examiner (1. polymer, 2. a therapeutic or diagnostic agent, and 3. a cell uptake promoter), and it is respectfully submitted that the invention includes these three components.

In the previous Office Action, the Examiner did not indicate that Applicants were required to elect a cell uptake promoter. If the Examiner is now indicating that this is a further requirement, i.e., that Applicants elect a cell uptake promoter, then Applicants elect the cell uptake promoter “biotin” with traverse. This election is with traverse as it is respectfully submitted that examination of all cell uptake promoters would not be unduly burdensome to the Patent Office.

Further, with respect to enablement, the Examiner is reminded that “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation.” *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP 2164.01 (8<sup>th</sup> Edition). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970); MPEP §2164.01(b) (8<sup>th</sup> Edition). “Nothing more than objective enablement is required, and therefore, it is irrelevant whether [a] teaching is provided broad terminology or illustrative examples.” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

It is respectfully submitted that one skilled in the art could make or use the invention as recited in the present claims from the disclosure in the patent without undue experimentation. In support of this position, the Examiner’s attention is directed to page

15 paragraph 26 to page 17, paragraph 29 which describe polymers, cell uptake promoters and therapeutic/diagnostic agents for use in the present invention; page 27, paragraph 66, which describes preferred embodiments of a therapeutic agent, polymer and cell uptake promoter; and the Examples which provide methods of making and using the compositions recited in claim 69 which include a polymer, a therapeutic or diagnostic agent, and at least one cell uptake promoter.

In view of the above, the Examiner is respectfully requested to remove the 35 U.S.C. §112, 1<sup>st</sup> paragraph rejection of the pending claims, as the specification discloses at least one method of making and using the claimed invention that correlates to the entire scope of the claim.

**D. 35 U.S.C. §112, 2<sup>nd</sup> Paragraph**

Claims 69-107 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner stated that in the reply filed 4/13/2004, “applicant has stated that the elected invention is the conjugation of two compounds, PEG conjugated to a retro inverso peptide (i.e. namely SEQ ID NOS:1-8), and this statement indicates that the invention is different from what is defined in the claim(s) because the claims (see claim 69) teach the conjugation of three compounds (1. polymer, 2. a therapeutic or diagnostic agent, and 3. a cell uptake promoter). Further, the Examiner stated that “[i]t is unclear whether the invention is a method for delivering a polymer conjugated to a therapeutic agent, the latter which is also conjugated to a cell uptake promoter; or a polymer conjugated to both therapeutic agent and a cell uptake enhancer? Applicant is asked to clarify which of the above is the invention, if either is the invention; or amend the claims commensurate in line with the election of the invention (two compounds conjugate; of which Applicant must further define whether the retro inverso protein (i.e., SEQ ID NOS: 1-8) is a therapeutic agent or a cell uptake promoter.”

This rejection is traversed. Applicant has not stated that the elected invention is the conjugation of two compounds, but has only elected two of the compounds as requested by the Examiner in the previous Office Action. It is respectfully submitted that

the elected invention includes a polymer, a therapeutic or diagnostic agent, and at least one cell uptake promoter, wherein at least one cell uptake promoter is bound to the therapeutic or diagnostic agent; or to the polymer. This language is clearly supported by the specification e.g., in the Abstract; pages 15-16, paragraph 26 of the specification; and throughout the specification.

Further, with respect to the Examiner requesting that Applicant further define whether the retro inverso peptide (i.e., SEQ ID NOS: 1-8) is a therapeutic agent or a cell uptake promoter, Applicants submit that in accordance with the previous response, the retro inverso peptide is the elected therapeutic agent. For further clarify this election, the term “retro inverso peptide” has been removed from claim 91; claims 92 and 95 have been cancelled without prejudice; and the term “cell uptake promoter peptide” and “uptake enhancer” have been removed from claims 106 and 107 respectively.

Should the Examiner require the election of a cell uptake promoter, as stated above with respect to the 35 U.S.C. 112, first paragraph rejection, Applicants elect biotin with traverse as it is respectfully submitted that examination of cell uptake promoters as a generic class would not be unduly burdensome to the Patent Office.

In view of the above, the Examiner is respectfully requested to remove the 35 U.S.C. §112, 2<sup>nd</sup> paragraph rejection of the pending claims.

If in the event the Examiner considers further issues regarding the elected invention and the present claims, the Examiner is invited to contact the undersigned below to address any outstanding issues in order to move this case forward.

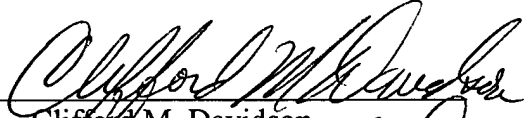
It is believed that no fee is due for this response. If it is determined that any fee is due, the Examiner is specifically authorized to charge said fee to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly solicited.

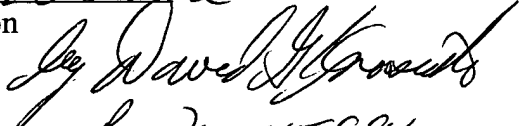
Respectfully submitted,

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